IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE

| MARYE WAHL, |) | |
|---------------------------|---|------------------------|
| Plaintiff, |) | |
| v. |) | |
| |) | |
| GENERAL ELECTRIC COMPANY, |) | Case No. 3:13-cv-00329 |
| GE HEALTHCARE, |) | Judge Trauger |
| GE HEALTHCARE AS, |) | |
| GE HEALTHCARE, INC., |) | |
| |) | |
| Defendants. |) | |

PLAINTIFF'S MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

PRELIMINARY STATEMENT

Marye Wahl has nephrogenic systemic fibrosis ("NSF"). (Plaintiff's Statement of Additional Undisputed Facts ("PSAUF") ¶ 25, Exhibit A.) This awful systemic disease causes hardening or fibrosis of the body's organs. Often this fibrosis leads to death. The disease is most visible in the body's largest and most visible organ, the skin. It presents as a terribly disfiguring skin condition that looks and feels like leather over a hardened wooden baseball bat. It is progressive and leads to contractures of the joints and causes an inability to move the joints and walk. Treatments for this rare disease are very few, marginally effective, and terribly expensive.

NSF has only one accepted cause: administration of gadolinium based contrast agents ("GCBAs") to patients with seriously impaired renal function. No known cases of NSF occurred before the advent of GBCAs and there are no known cases of a person contracting the disease since physicians were properly advised in the proper administration of GBCAs in patients with seriously impaired renal function. The graph attached as Exhibit B starkly illustrates the incidence of NSF before and after GEHC finally warned of the real risks of its product including

the addition in February 2007 of a black box warning of the risk of NSF that GBCAs pose to renally impaired patients. Tragically, Marye's administrations of Omniscan occurred in May and November 2006, (PSUFA ¶¶ 22, Exhibits C and D) before the medical community was warned of the real risks associated with Omniscan. The discontinuation of use of Omniscan in patients with severe renal disease has eliminated new incidents of this dreadful disease, but came too late for Marye.

Albeit far too late in coming, the medical community's awareness of the cause of NSF was a positive development medically. However, it has left little incentive for researchers to find a cure or even treatment for the disease. Thus, those like Marye are left to suffer with the disease with no real hope of a cure or effective treatment. Marye's treating physician at Vanderbilt University Medical Center "expect[s] her course to be an arduous one and further pain care to be ongoing." (Exhibit E.)

Defendants' GBCA Omniscan is the only known GBCA ever administered to Marye. Omniscan has the most reported cases of NSF (Exhibit I p. 27) even though it did not have the largest share of the GBCA market. As a result of her administration of Omniscan, Marye has a permanent, debilitating, potentially fatal, and incurable disease. NSF has and will continue to have a profound impact on Marye Wahl's life. Exhibits E, F, and G, letters from Marye's physicians and employer, are testaments to her strength of character and perseverance, but also to the profound and progressive impact NSF is having on her life.

Against this backdrop Defendants have moved for summary judgment on the basis of a draconian Tennessee statute of repose, arguing that Marye's right of action was extinguished years before she was even diagnosed with NSF. Courts have recognized the draconian nature of the statute of repose Defendants have invoked here. In *Montgomery v. Wyeth*, 540 F.Supp.2d

933 (E.D.Tenn. 2008), Judge Collier took the highly unusual step of encouraging the Tennessee Legislature to consider amending the statute due to the harsh outcomes in compels in some cases. He wrote:

Rarely does this Court suggest that a legislative body reconsider one of its enactments. The Court believes its role is simply to apply the law applicable to the case before it and not concern itself with the merits of the case. However, because of the result in this case, this is one of those rare cases where the Court believes it is appropriate to urge the Tennessee legislature to look closely at the law governing this case.

Id. at 936.

If Defendants motion were to be successful, Marye would be entirely deprived of a remedy. She would be left in a hopeless state, with no hope for a cure, no hope for treatment breakthroughs, and no hope for anything resembling a normal life or financial security. However unlike Judge Collier in the *Montgomery* case, this Court is not constrained to apply this statute of repose and can easily avoid imposing the unjust outcome required in *Montgomery*. Due to applicable choice of law rules that were not at issue in *Montgomery* or any of the cases Defendants rely upon, the Tennessee statute of repose does not apply in this action. Further, due to Defendants' inadequate record keeping, even if the statute could be applied, Defendants have left a gaping factual hole in their motion that precludes entry of summary judgment.

SUMMARY OF ARGUMENT

Defendants' motion for summary judgment, based solely on the Tennessee statute of repose ("TSOR"), Tenn.Code Ann. § 29-28-103(a), must be denied for three independent reasons. First, New Jersey substantive law governs this action and New Jersey has no applicable statute of repose. Second, assuming *arguendo* Tennessee substantive law generally applies, applicable Ohio choice of law rules bar application of the TSOR because the TSOR violates

Ohio public policy. Third, assuming *arguendo* the TSOR could be applied here without violating Ohio public policy, Defendants' motion for summary judgment fails to allege facts, let alone support them by evidence in the record, necessary to establish the TSOR affirmative defense.

First, New Jersey substantive law applies. The parties agree that Ohio choice of law rules govern this action. Ohio choice of law rules require application of New Jersey substantive law because the state and federal standards and oversight of GEHC's handing of Omniscan occurred primarily in New Jersey. Where, as here, there is a potential lengthy period between exposure to an FDA regulated drug and subsequent commencement of a civil action, and a defendant distributed a uniform drug internationally and issued a uniform set of warnings and instructions for use, actions for personal injury arising from the drug are governed by the substantive law of the state in which application of the federal standards and oversight occurred. *See In re Bendectin Litig.*, 857 F.2d 290 (6th Cir.1988). *Bendectin* requires application of New Jersey substantive law.

Second, assuming *arguendo* Tennessee substantive law generally applies, the TSOR, if applied here, would have extinguished Plaintiff's cause of action after it vested but before she commenced her action, which violates a fundamental Ohio public policy. Therefore, governing choice of law rules prohibit applying the TSOR in this action. If Ohio choice-of-law rules call for application of Tennessee rather than New Jersey substantive law, they do so only insofar as *Tennessee substantive law does not violate Ohio public policy. Am. Interstate Ins. Co. v. G & H Serv. Ctr., Inc.*, 112 Ohio St.3d 521, 861 N.E.2d 524, 2007 -Ohio- 608 (Ohio 2007). Ohio has a strong public policy in favor of granting injured persons with vested claims a right to a remedy and against permitting statutes of repose from extinguishing vested (as opposed to inchoate) causes of action. This strong public policy has been rooted in the Ohio Constitution since 1802.

Ruther v. Kaiser, 983 N.E.2d 291, 294 (Ohio 2012). Here, Plaintiff first exhibited symptoms - later determined to be consistent with NSF - in 2007. (PSAUF ¶ 23, Exhibit H.) Her claim vested under Tennessee law at that time. See Estate of Bell v. Shelby County Health Care Corp., 318 S.W.3d 823 (Tenn. 2010) (holding right to claim vests at time of injury). See also T. C. A. § 28-3-104(b)(1) (product liability action accrues "at time of injury"). GEHC says the statute of repose extinguished Plaintiff's cause of action after 2007. Because the TSOR, if applied in this manner, would have extinguished a vested cause of action in violation of a fundamental public policy of Ohio, governing choice of law rules bar application of the TSOR in this action. See Ruther v. Kaiser, 983 N.E.2d 291, 295 (Ohio, 2012) (explaining "right to remedy" provision in Ohio Constitution protects vested causes of action from extinguishment by statute of repose, but does not protect inchoate, i.e., not yet vested, causes of action from extinguishment by statute of repose).

Third, assuming *arguendo* that Tennessee rather than New Jersey substantive law applies and that the TSOR could be applied here without violating Ohio public policy, the motion fails to allege facts, let alone facts supported by evidence in the record, necessary to establish the TSOR affirmative defense. Defendants have failed to satisfy their burden because their motion depends entirely on unsupported speculation that the Omniscan administered to Marye Wahl in May and November 2006 was manufactured on or after January 1, 2004. Defendants provide no evidence in support of this speculation. Yet it is undisputed that Omniscan has been manufactured since 1993, (PSAUF ¶ 17, Exhibit I), that GEHC used a third party distributor to distribute Omniscan to the facility where Plaintiff was administered Omniscan, (FSAUR ¶ 34, Exhibit J), and that GEHC does not know who distributed the Omniscan administered to Mary Wahl. (*Id.*) It follows that GEHC does not know (or at least has not told Plaintiff or the Court) when the

Omniscan administered to Marye Wahl was manufactured or what its anticipated life was. GEHC's evidence that all Omniscan manufactured *between 2004 and 2006* had an expiration date of two years is probative of nothing absent evidence that the Omniscan administered to Marye Wahl was manufactured during that time frame. Because there is absolutely no evidence of the manufacture date or anticipated life of the Omniscan administered to Marye Wahl, Defendants' motion must be denied.

SUMMARY JUDGMENT STANDARD

Summary judgment shall not be granted unless "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." *Cardinal Health 414, Inc. v. Adams*, 582 F.Supp.2d 967, 975 (M.D.Tenn. 2008). In determining whether the moving party has met its burden, the court must view the factual evidence and draw all reasonable inferences in the light most favorable to the non-moving party. *Id.*

Where, as here, "the crucial issue is one on which the movant will bear the ultimate burden of proof at trial, summary judgment can be entered only if the movant submits evidentiary materials to establish all of the elements of the claim or defense." *Vance v. Latimer*, 648 F.Supp.2d 914, 919 (E.D.Mich.2009), citing *Stat-Tech Liquidating Trust v. Fenster*, 981 F.Supp. 1325, 1335 (D.Colo.1997), *United States v. Four Parcels of Real Property in Greene and Tuscaloosa Counties in State of Ala.*, 941 F.2d 1428, 1438 (11th Cir.1991), and *Resolution Trust Corp. v. Gill*, 960 F.2d 336, 340 (3d Cir.1992). That is, when the moving party bears the ultimate burden of persuasion, the movant's affidavits and other evidence not only must show the absence of a material fact issue, they also must carry that burden. *Vance*, 648 F.Supp.2d at 919, citing *Stat–Tech Liquidating Trust v. Fenster*, 981 F.Supp. 1325, 1335 (D.Colo.1997). GEHC

acknowledges this burden, stating that a "defendant moving for summary judgment can carry its burden by *conclusively establishing* an affirmative defense through materials in the record or included with the motion" (emphasis added). Doc. No. 36, Defendants' Memo. in Support of Motion for Summary Judgment, p. 3, citing Rule 56 and *Thomas v. Speedway SuperAmerica*, *LLC*, 506 F.3d 496, 502 n.2 (6th Cir. 2007).

The TSOR is an affirmative defense. Tenn. Rules Civ. Proc., Rule 8.03. The TSOR provides, in pertinent part, that a product liability action "must be brought . . . within one (1) year after the expiration of the anticipated life of the product . . ." Tenn.Code Ann. § 29-28-103(a). The anticipated life of a product is "determined by the expiration date placed on the product by the manufacturer when required by law but shall not commence until the date the product was first purchased for use or consumption." Tenn.Code Ann. § 29-28-102(1). Tennessee Rule 8.03 was amended effective July 1, 2006 to expressly list the statute of repose as an affirmative defense. See Advisory Commission Comment to 2006 Amendment; see also Pratcher v. Methodist Healthcare Memphis Hospitals, --- S.W.3d ----, 2013 WL 3270836, at * 6 (Tenn.). However, the statute of repose was an affirmative defense under Rule 8.03 even before its explicit listing. Id. at 9. Because the statute of repose is an affirmative defense, Defendant has the burden of proof to establish the statute of repose bars Plaintiff's claims. Woodard v. Gross, No. W2011–02316–COA–R3–CV, 2012 WL 3893519, at *8 (Tenn.Ct.App. Sept. 10, 2012) ("[A] defendant who relies on an affirmative defense, such as the statute of repose, in a summary judgment motion, must point to undisputed facts that establish the defense."), quoted approving in *Pratcher* at * 7 and n.10.

ARGUMENT

I. THE TENNESSEE STATUTE OF REPOSE DOES NOT APPLY IN THIS ACTION UNDER GOVERNING CHOICE OF LAW RULES

Ohio choice of law rules govern because Plaintiff filed this action directly into MDL 1909 in the United States District Court for the Northern District of Ohio. *Byers v. Lincoln Elec. Co.*, 607 F.Supp.2d 840, 844 (N.D. Ohio 2009). See also *In re Vioxx Prods. Liab. Litig.*, 478 F.Supp.2d 897, 904 (E.D. La. 2007) (concluding that the filing of a case directly in the MDL court "suggests that the Court should apply the law of the state in which [the MDL] sits"). GE concedes Ohio choice of law rules govern. Doc. No. 36, Defendants' Memo. in Support of Motion for Summary Judgment, p. 4.

A. NEW JERSEY SUBSTANTIVE LAW GOVERNS THIS ACTION

Ohio choice of law rules require application of New Jersey substantive law in this action. The Ohio Supreme Court abandoned strict adherence to "the traditional rule of *lex loci delicti* in favor of a more flexible rule based on which state has 'a more significant relationship to the lawsuit,' in light of the factors set forth in section 145 of *Restatement (Second) of Conflict of Laws* § 145 (1971)." *In re Bendectin Litigation*, 857 F.2d 290, 304 (6th Cir. 1988) quoting *Morgan v. Biro Mfg. Co.*, 474 N.E.2d 286 (Ohio 1984) (internal citation omitted).

New Jersey substantive law governs because New Jersey has a more significant relationship to this action than does Tennessee. The Sixth Circuit's *In re Bendectin* opinion stemmed from an MDL in a federal court in Ohio involving hundreds of personal injury claims brought throughout the United States on behalf of children born with physical abnormalities arising from their in vivo exposure to a prescription drug. *In re Bendectin Litigation*, 857 F.2d at 293. The Sixth Circuit affirmed the district court's determination that Ohio law governed all plaintiffs' claims. The court based its holding on the facts that the primary regulation of the labeling, research, and distribution of the drug occurred under Ohio law (the law of the state

where the drug was manufactured and where the defendant maintained its principal place of business) and the federal Food, Drug and Cosmetic Act. The court reasoned:

[Defendant] manufactured and distributed a uniform drug internationally. The company issued a uniform set of warnings and instructions for use. The regulations governing the labeling, research, and distribution of the drug were governed either by Ohio law or by the federal Food, Drug and Cosmetic Act. Standards against which defendant's wrongful or negligent conduct may be measured are also set by Ohio and federal law.

* * *

The State of Ohio is responsible for regulating local aspects of the marketing, manufacture, distribution, and labeling of the drug, and thus the relationship between the parties is essentially centered in Ohio, where the tortious conduct and the safety of the product are regulated.

Id. at 305.

The court discounted the importance of plaintiffs' domiciles, and states of prescription, ingestion, and injury due in part to the extensive FDA regulation. The court explained:

The fact that federal regulation through the FDCA impacts pervasively upon the development and approval of the drug in question tends further to minimize the significance of the law of other states and to focus emphasis upon the state of manufacture as the state in which application of the federal standards and oversight is most likely to occur.

Id. (emphasis added). Here, it is beyond dispute that federal regulation of Omniscan occurred primarily in New Jersey. GEHC maintains its headquarters in New Jersey. The Omniscan package inserts identify New Jersey as the home state of GEHC or its predecessors in interest in 1997, 2001, 2004, and 2007. (PSAUF ¶¶ 29-32, Exhibits K, L, M, and N.) In 2009, GEHC issued its "Omniscan Advisory Meeting Briefing Document" to the FDA. That document also indicates it originated in New Jersey. (PSAUF ¶ 33, Exhibit I.) The other Bendectin factors also favor application of New Jersey law. Omniscan, like the drug in Bendectin, was manufactured

and distributed internationally and was accompanied by a uniform set of warnings and instructions for use. PSAUF $\P\P$ 27 and 28, Exhibit I.)¹

The Sixth Circuit also discounted the importance of plaintiffs' domiciles, and states of prescription, ingestion, and injury because of the lengthy period of time between ingestion and commencement of a civil action, reasoning that the long period of time undermined the assumption that the state of domicile at the time suit was filed would necessarily be the same as the state of ingestion or injury. The court explained:

it is difficult if not impossible to perceive any meaningful relationship to the subject matter of the lawsuit for the law of the state of domicile at the time of the suit, or the state in which the drug may have been prescribed, dispensed, ingested, or the state in which the child may have been conceived, or born.

Id. at 305. Critically, the Sixth Circuit conducted a prospective analysis, asking whether it was "safe to assume" that a person who ingested in a particular state also resided in that state years later when injury occurred or suit was filed.²

Here, as in *Bendectin*, it was not safe to assume (prospectively, that is, at the time of administration of Omniscan) that a person who is administered Omniscan in a particular state is likely to suffer injury, be diagnosed, receive treatment, and file suit years later all while living in the same state. To the contrary, it is reasonable to expect a significant time lapse between

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¹ The *Bendectin* court found the state of "manufacture" important only because state of manufacturer determined the focal point of regulation of the defendant in the United States. That is, the Sixth Circuit used the state of manufacture as a proxy for the state where state and federal regulation of the defendant occurred. In this case, where Omniscan is manufactured overseas, New Jersey is the focal point of regulation because that is where GEHC maintains its principal place of business.

² Conceptually, this prospective analysis is analogous to a court's review of the reasonableness of a contractual liquidated damages clause. The court does not determine in retrospect whether the liquated damages are reasonable in relation to the harm actually suffered, but rather determines whether the liquidated amount was "reasonable in relation to the anticipated damages for breach, *measured prospectively at the time the contract.*" *Vanderbilt University v. DiNardo*, 174 F.3d 751, 755 (6th Cir. 1999) (emphasis added).

administration of Omniscan and commencement of a civil action because of the difficulty of diagnosing NSF. NSF is a rare disease, with fewer than 1500 cases reported cases of the disease worldwide. (PSAUF ¶ 18-19, Exhibit I.) It is a new disease; the first case was reported in 2000. (PSAUF ¶ 20, Exhibit I.) It attacks a tiny subset of the population, namely, persons with renal insufficiency. (Id. p. 9.) Under these circumstances, a long gap between administration and diagnoses and an even a longer gap between administration and commencement of a civil action is to be expected. By way of example, Marye Wahl was administered Omniscan in May and November 2006. (PSAUF ¶ 22, Exhibits C and D.) She showed symptoms recognized by her physician (but not disclosed to her) as potentially related to NSF in 2007. (PSAUF ¶ 23, Exhibit H.) She was diagnosed with NSF in 2010. (PSAUF ¶ 26, Exhibit A.) She file suit in 2011. Because of the long anticipated time lapse between administration of Omniscan and the filing of a civil action, *Bendectin* requires that little weight be given to the state of administration, injury, diagnoses, or domicile of the Plaintiff.³

The Sixth Circuit's opinion in *Montgomery v. Wyeth*, 580 F.3d 455 (6th Cir. 2009), is not to the contrary. In *Montgomery*, as here, the defendant in a pharmaceutical personal injury action moved for summary judgment based on the anticipated life provision of the TSOR. The plaintiff argued for application of Georgia law on the basis that she purchased the drug from a third party in Georgia. *Id.* at 460. The defendant argued Tennessee law applied because Tennessee was where plaintiff sustained her injury, was her place of domicile and residence, was where she intended to and did use almost all of the drug at issue, and was the state where she was

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³ Because the *Bendectin* court performed a prospective analysis, it is no answer for GEHC to say that we know that Marye Wahl was administered Omniscan, was injured, was diagnosed, and commenced her action all while living in Tennessee. Undoubtedly, had the *Bendectin* court applied such a retrospective analysis, it would have been able to determine for many plaintiffs the state in which the drug was prescribed, dispensed, ingested, and the state in which the child was conceived and born.

diagnosed and treated for her injury. *Id.* at 460. As between the two choices advanced by the parties, Tennessee and Georgia, the court found application of Tennessee law proper because "the evidence does not establish that Georgia's contacts were more significant than Tennessee's."

Id. at 460. The Court distinguished *Bendectin* on the grounds that the drug at issue in *Montgomery* was manufactured in Virginia and the defendants maintained their principal places of business in Pennsylvania and New Jersey. *Id.* at 462. Thus, the court found *Bendectin* provided no support for application of Georgia law.

Montgomery shows that rumors of Bendectin's death were greatly exaggerated. Prior to Montgomery, courts had questioned the continued vitality of the Sixth Circuit's choice of law analysis in Bendectin. See, e.g., In re Telectronics Pacing Systems, Inc., 172 F.R.D. 271, 291 n.13 (S.D.Ohio 1997) ("We, however, question the correctness of that ruling and further question the continuing validity of that holding in light of the Sixth Circuit's later ruling in In re American Medical Systems"). In Montgomery, however, the Sixth Circuit embraced its choice of law analysis in Bendectin, but distinguished that opinion on the basis that Georgia was not the place of manufacture or principal place of business of the defendant, and therefore was not the focal point of regulation of the drug. In light of Montgomery, Bendectin remains good law unless and until the Sixth Circuit disavows the holding in that case.

B. ASSUMING ARGUENDO TENNESSEE SUBSTANTIVE LAW GENERALLY APPLIES, OHIO CHOICE OF LAW RULES PRECLUDE APPLICATION OF THE TSOR BECAUSE THE TSOR AS APPLIED HERE WOULD VIOLATE OHIO PUBLIC POLICY

Assuming *arguendo* Ohio choice-of-law principals call for application of Tennessee substantive law, Tennessee substantive law would apply only *insofar as it does not violate Ohio public policy*. The Ohio Supreme Court has adopted the choice-of-law approach set out by the *Restatement (Second) of the Law of Conflicts*, including the public policy exception. *Am*.

Interstate Ins. Co. v. G & H Serv. Ctr., Inc., 861 N.E.2d 524, 526-28 (Ohio 2007). Section 90 of the Restatement reads, "No action will be entertained on a foreign cause of action the enforcement of which is contrary to the strong public policy of the forum," quoted in Am. Interstate Ins. Co., 861 N.E.2d at 528. "The public-policy concerns are essentially the same whether the question is one of applying foreign law or bringing a foreign action." Id. at 528. Therefore, even if the Restatement factors provide that Tennessee law governs Plaintiff's claims, it is still necessary to determine whether allowing GEHC to assert its TSOR defense in this action would violate Ohio's public policy. Id.

Ohio choice of law rules bar application of foreign laws that violate Ohio public policy where applying such law would either prejudice the interests of any Ohio citizens or undermine the state's public policy. *See Id.* ("They have required that the foreign right that a party seeks to enforce must be 'contrary to good morals, or natural justice, or prejudicial to the best interests of the citizens of the forum state"). Here, while the parties are not Ohio citizens, the Ohio public policy exception applies because application of the TSOR would undermine a fundamental public policy of Ohio.

Ohio public policy prohibits application of a statute of repose in a manner that extinguishes vested rights. The Ohio Constitution, Article I, Section 16, guarantees that "[a]ll courts shall be open, and every person, for an injury done him in his . . . person . . . shall have remedy by due course of law, and shall have justice administered without denial or delay." "[T]he right-to-remedy clause provides that the court shall be open for those to seek remedy 'by due course of law." Ruther v. Kaiser, 983 N.E.2d 291, 294 (Ohio 2012) (emphasis added in Ruther). The right to remedy provision has been a part of the Ohio Constitution since 1802 when Ohio was admitted to the union and appears in Ohio's Bill of Rights. *Id*.

The right to remedy provision applies to existing, vested rights and prohibits a statute of repose from extinguishing such rights. See *id.* at 295-96. In *Ruther*, a medical malpractice action, Plaintiff argued that the Ohio medical malpractice statute of repose violated the right to remedy provision of the Ohio Constitution because that statute extinguished Plaintiff's right of action after the right had vested. However, the Ohio Supreme Court explained that under Ohio law, a cause of action for medical malpractice does not vest "until a patient discovers or in the exercise of reasonable care and diligence should have discovered the resulting injury." *Id.* at 295. The Court held that the statute of repose did not violate the right to remedy provision because plaintiff's claim had not vested at the time it was extinguished by the statute of repose. *Ruther* makes clear that Ohio public policy prohibits applying a statute of repose to bar a vested right but does not prohibit applying a statute of repose to bar an inchoate, or unvested, right.

Under Tennessee law, a cause of action vests at the time of injury, not at the time of discovery that an injury was wrongfully caused. In *Estate of Bell v. Shelby County Health Care Corp.*, 318 S.W.3d 823 (Tenn. 2010), defendant negligently failed to advise decedent's physicians of the results of an August 19, 2002 electrocardiogram ("EKG"). *Id.* at 826-27. On December 12, 2002, decedent died of a heart attack and her child was born with brain damage. *Id.* at 826. On May 21, 2003, the Tennessee Legislature passed a statute which purported to apply to all cases filed on or after July 1, 2003 that – if given effect in the case – would have capped the amount defendant could be held liable to pay in damages. *Id.* Plaintiffs filed suit on behalf of the decedent and the child in December 2003. *Id.* Critically, the court's careful recitation of the timeline did not address when the plaintiffs knew or should have known that defendant's negligent failure to inform decedent's physicians of the EKG results caused decedent's death and the child's injuries. The nature of the negligence, failure to convey certain

information to a decedent's treating physicians, logically requires that injury precede discovery of the negligence by some period of weeks or months.

The Tennessee Supreme Court barred retroactive application of the statute as violating a constitutional prohibition against retrospective laws that impair vested rights. As in Ruther, surpa, the outcome of Estate of Bell turned on when plaintiffs had a vested right to their medical malpractice claims. The court explained, "Distilled to its essence, the question is whether the . . . plaintiffs' right to seek damages, unlimited by the [new statute's] cap, vested when the [defendant's] tortious conduct and the . . . plaintiffs' injuries occurred. We conclude that the . . . plaintiffs' right of action to pursue damages without the [new statute's] cap on damages vested prior to the General Assembly's approval of the 2003 amendment." Id. at 830. The Court further explained, "In our application of Article I, Section 20 to tort actions, we have repeatedly found that the rights of the plaintiff vest or accrue with the commission of the tort and the resulting injury to the plaintiff." Id. at 833 (emphasis added). The court quoted with approval Cherry v. Williams, 36 S.W.3d 78, 83 (Tenn.Ct.App.2000) which noted that "[a]s a general rule, a cause of action for an injury accrues when the injury occurs, an 'injury' being understood as any wrong or damage done to another's person, rights, reputation, or property." Estate of Bell at 830. Estate of Bell establishes that under Tennessee law, a potential claim becomes a vested right when the wrongful conduct and injury occur, not at some later time when the cause of action is or should have been discovered. That the discovery rule tolls the running of the statute of limitations until the plaintiff knows or should know of a wrongfully caused injury does not change the fact that vesting occurs upon injury, not discovery of the cause of action.⁴

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⁴ In another case, the Tennessee Supreme Court has explained that "Where the injury occurs within the [repose] period, and a claimant commences his or her action after the [repose] period has passed, *an action accrues* but is barred." *Penley v. Honda Motor Co., Ltd.*, 31 S.W.3d 181,

In sum, Ohio public policy engrafted in the Ohio Constitution provides that once a claim vests it cannot be extinguished by a statute of repose. Under Tennessee law, a cause of action vests at the time of injury (and thus often before discovery). The result in this case is that Plaintiff's claim vested in 2007 under applicable Tennessee law because that is when her symptoms consistent with NSF first manifested. (PSAUF ¶ 23, Exhibit H.) Thus the TSOR cannot be applied because it would violate Ohio public policy. While this choice of law analysis is not as straightforward as a typical choice of law analysis, courts have recognized that a plaintiff's direct filing into an MDL outside of plaintiff's district of residence (as happened here) can give rise to odd choice of law analyses. See, e.g., *In re Vioxx Products Liability Litigation*, 478 F.Supp.2d 897, 904 n.2 (E.D.La.,2007).

II. ASSUMING ARGUENDO THE TSOR APPLIES IN THIS ACTION, DEFENDANTS' SUMMARY JUDGMENT MOTION DOES NOT ESTABLISH THAT THE TSOR BARS PLAINTIFF'S CLAIM

Defendants' motion also fails because it depends entirely on unsupported speculation, namely, that the Omniscan administered to Plaintiff was manufactured on or after January 1, 2004. This assumption is entirely unwarranted. GE or its predecessor in interest began manufacturing Omniscan in 1993, not in 2004. (PSAUF¶ 17, Exhibit I.) Defendants say:

From 2004 through 2006, all Omniscan was manufactured by GE Healthcare in Cork, Ireland. (SUMF, ¶ 4.)

184 (Tenn. 2002) (emphasis added), quoting *Gillam v. Firestone Tire & Rubber Co.*, 241 Neb. 414, 489 N.W.2d 289, 291 (1992) (citations omitted by Tennessee Supreme Court). *Penley* establishes that under Tennessee law a cause of action vests at the time of injury. While Tennessee might permit a statute or repose to extinguish such a vested claim, such an outcome violates Ohio public policy – which is dispositive here.

⁵ There is no legally significant difference between the meaning of "vested right" for the purpose of the Tennessee's prohibition on retroactive laws impairing vested rights and Ohio's prohibition on statutes of repose extinguishing vested rights.

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This does not establish the Omniscan administered to Marye Wahl was manufactured between 2004 and 2006.

All finished dosages of Omniscan shipped to the United States from the Cork, Ireland, plant from 2004 through 2006 bore an expiration date. (SUMF, ¶ 5.)

This does not establish the Omniscan administered to Marye Wahl was manufactured between 2004 and 2006.

During that time frame, the expiration date for every finished Omniscan dosage shipped to the United States was two years from the respective date of manufacture. (SUMF, \P 6.)

This does not establish the Omniscan administered to Marye Wahl was manufactured between 2004 and 2006.

This two-year expiration date was present regardless of packaging. (SUMF, \P 7.)

This does not establish the Omniscan administered to Marye Wahl was manufactured between 2004 and 2006. Defendants conclude:

Based upon the dates of Plaintiff's scans, May 8, 2006, and November 1, 2006, the latest possible expiration dates for the two dosages of Omniscan that Plaintiff received would be May 8, 2008, and November 1, 2008, respectively. (SUMF, ¶ 8.)

This conclusion assumes what GE has not proven, or even alleged, namely, that the Omniscan administered to Marye Wahl was manufactured between 2004 and 2006. Defendants provide no evidence in support of this speculation. Yet it is undisputed that Omniscan has been manufactured since 1993, (PSAUF ¶ 17, Exhibit I), that GEHC used a third party distributor to distribute Omniscan to the facility where Plaintiff was administered Omniscan, (PSAUF ¶ 34, Exhibit J), and that GEHC does not know who distributed the Omniscan administered to Mary Wahl. (PSAUF ¶ 35.) It follows that GEHC does not know (or at least has not told Plaintiff or

the Court) when the Omniscan administered to Marye Wahl was manufactured or what its anticipated life was. GEHC's evidence that all Omniscan manufactured *between 2004 and 2006* had an expiration date of two years is probative of nothing absent evidence that the Omniscan administered to Marye Wahl was manufactured during that time frame.

Defendants bear the burden of production and persuasion because they seek summary judgment on the basis of an affirmative defense. They can prevail only by, in their words, "conclusively establishing an affirmative defense through materials in the record or included with the motion." There is absolutely no evidence of the manufacture date or anticipated life of the Omniscan administered to Marye Wahl. Therefore, Defendants' motion must be denied.

III. ALTERNATIVE REQUEST FOR DISCOVERY

The facts of record conclusively establish that New Jersey substantive law governs this action and therefore Defendants' motion must be denied. Even if the record were not adequate to establish New Jersey substantive law applies, Defendants bear the burden of proof on this motion and have certainly not presented evidence sufficient to permit a conclusive finding that Tennessee law governs. They did little more than assume that the place of administration and injury determines what substantive law governs. Ohio choice of law rules reject this assumption. In the event this Court finds the current record inadequate to conclude New Jersey substantive law applies, Plaintiff respectfully requests the opportunity to conduct discovery and supplement the record with additional evidence relevant to the choice of law analysis.

Defendants have not established the date of manufacture or expected life of the Omniscan administered to Mary Wahl and thus have not established the TSOR – even if it were applicable in this action – bars Plaintiff's claim. In the event Defendants are permitted to supplement the record with additional facts, which Plaintiff does not concede is proper on a reply memorandum,

Plaintiff respectfully requests the opportunity to conduct discovery to challenge any new evidence and otherwise respond to and test the veracity of the evidence presented by Defendants, including the Declaration of Danny Healy.

CONCLUSION

For the foregoing reasons, Plaintiff prays this Court deny Defendants' Motion for Summary Judgment and issue such other or further relief as is proper, including authorizing discovery as deemed necessary by the Court to develop additional facts, if any, necessary to resolve this motion.

Dated: July 22, 2013 Respectfully submitted,
TORHOERMAN LAW LLC

/s/Eric Terry

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ATTORNEYS FOR PLAINTIFF

CERTIFICATE OF SERVICE

The undersigned certifies that I served this notice via electronic filing to each person to whom it is directed or email for those not set up for electronic filing on this 22nd day of July 2013.

| /s/ Kristie | Stephens | |
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| / 5/ IX II 5 LI C | MEDITORS | |

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